Receipt helphoserti 03408 200 prondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents, P.O. Box 1450, Alexandria, VA

22313-1450 on March 6, 2007

Attorney Docket No. CHM-022M

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

e Application of

Eric James WALL et al.

Confirmation No: 8939

Serial No.: 10/597,997

Filed:

August 15, 2006

Title:

INJECTION DEVICE FOR ADMINISTERING A VACCINE

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 CFR §§1.56, 1.97 and 1.98, Applicant request the Examiner to make of record the documents listed on the attached PTO/SB/08 form in connection with examination of the aboveidentified patent application. As provided in §1.97(g), no representation is made or intended that a thorough art search was made. As provided in 37 C.F.R. §1.97(h), this Information Disclosure Statement does not constitute an admission of any kind, and specifically is not an admission that the documents listed on attached form PTO/SB08 are, or are considered to be, material to the patentability of the above-identified patent application, as defined in 37 C.F.R. §1.56(b). In accordance with 37 C.F.R. §1.98(a)(2), Applicants are submitting copies of foreign patent documents and non-patent literature.

This information disclosure statement is being submitted under 37 C.F.R. §1.97(b)(3). Applicants have not received an Office Action on the merits in the present application. Therefore, no fee is believed to be due.

Applicants also respectfully request the Examiner to consider and make of record the co-pending applications listed on the attached page.

Receipt thate: 03/08/2007

Sheet

Attorney Docket No. CHM-022M

STATEMENT BY APPLICANT

(use as many sheets as necessary)

of

5

2

Filing Date	08/15/2006	
First Named Inventor	Eric James Wall	
Art Unit		
Examiner Name		
Attorney Docket Number	CHM-022M	

Application Number

Complete if Known

10/597,997

Examiner	Cite	Document Number		Dublication D. t.	Name of Bata of	Pages, Columns, Lines, Where
Initials*	No.1	ļ	er - Kind Code² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		US-	5,318,557	06/07/1994	Gross	
		US-	5,336,188	08/09/1994	Kriesel	
		US-	5,352,201	10/04/1994	Jemmott	
		US-	5,354,287	10/11/1994	Wacks	
		US-	5,419,771	05/30/1995	Kriesel	
		US-	5,478,315	12/26/1995	Brothers et al.	
		US-	5,527,288	06/18/1996	Gross et al.	
		US-	5,527,287	06/18/1996	Miskinyar	
		US-	5,578,014	11/26/1996	Erez et al.	
		US-	5,616,123	04/01/1997	Cheikh	
		US-	5,616,128	04/01/1997	Meyer	1
		US-	5,616,132	04/01/1997	Newman	
		US-	5,656,032	08/12/1997	Kriesel et al.	1
		US-	5,681,291	10/28/1997	Galli	
		US-	5,693,018	12/02/1997	Kriesel et al.	
		US-	5,695,463	12/09/1997	Cherif-Cheikh	
		US-	5,704,520	01/06/1998	Gross	<u> </u>
		US-	5,704,911	01/06/1998	Parsons	
	-	US-	, 5,735,818	04/07/1998	Kriesel et al.	
		US-	5,762,634	06/09/1998	Davis	1
		US-	5,785,688	07/28/1998	Joshi et al.	
		US-	5,791,466	08/11/1998	Tsals	
		US-	5,800,420	09/01/1998	Gross et al.	
		US-	5,807,375	09/15/1998	Gross et al.	
		US-	5,814,020	09/29/1998	Gross	
		US-	5,820,622	10/13/1998	Gross et al.	
Ψ.		US-	5,848,991	12/15/1998	Gross et al.	
		US-	5,848,990	12/15/1998	Cirelli et al.	
		US-	5,858,001	01/12/1999	Tsals et al.	
		US-	D-404,366	01/19/1999	Gross et al.	
		US-	D-404,482	01/19/1999	Falk et al.	
		US-	D-405,524	02/09/1999	Falk et al.	
1		US-	5,871,125	02/16/1999	Gross	
		US-	5,885,250	03/23/1999	Kriesel et al.	
		US-	5,921,963	07/13/1999	Erez et al.	
		US-	5,931,814	08/03/1999	Alex et al.	
		US-	5,957,895	09/28/1999	Sage et al.	

Examiner Signature	/Nathan Price/	Date Considered	02/09/2009
-----------------------	----------------	--------------------	------------

Receipt date: 03/08/2007

MAR 0 8 2007

10597997 - GAU: 3763

Attorney Docket No. CHM-022M

does not constitute an admission that each or all of the listed documents are material or constitute "prior art." If the Examiner applies any of the documents as prior art against any claim in the application and Applicant determines that the cited documents do not constitute "prior art" under United States law, Applicant reserves the right to present to the office the relevant facts and law regarding the appropriate status of such documents.

Respectfully submitted,

Ву

Daniel F. Nesbitt Attorney for Applicant Registration No. 33,746

(513) 229-0383

Customer Number 38155

March 6, 2007

ှင်မြို့ ရှေ့ (03/08/2007

	A	tto	mey	Docket	No.	CHM-022M
01	_	; <u>f</u>	<i>V</i>	0.10.11		

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	5

	Attorney Docket No. CHM-022M			
Complete if Known				
Application Number	10/597,997			
Filing Date	08/15/2006			
First Named Inventor	Eric James Wall			
Art Unit				
Examiner Name	•			
Attorney Docket Number	CHM-022M			

			U.	S. PATENT DO	CUMENTS	
Examiner Initials*	Cite No.1	Numl	Document Number ber - Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant
	-	US-	2,671,488	03/09/1954	Harnisch	Figures Appear
	<u> </u>	US-	3,066,670	12/04/1962	Stauffer	
		US-	3,572,336	03/23/1971		
		US-	3,605,742	09/20/1971	Hershberg Tibbs	
	i	US-	3,702,608	11/14/1972	Tibbs	
		US-	4,031,889	06/28/1977	Pike	<u> </u>
***		US-	4,043,333	08/23/1977	Munsch	·
		US-	4,085,748	04/25/1978	Boyer	<u> </u>
		US-	4,194,505	03/25/1980	Schmitz	<u> </u>
• • • • • • • • • • • • • • • • • • • •		US-	4,196,732	04/08/1980	Wardlow	
		US-	4,214,584	07/29/1980	Smirnov et al.	ļ
		US-	4,227,528	10/14/1980		
		US-	4,267,836	05/19/1981	Wardlow	
		US-	4,270,537		Whitney et al.	
	-	US-	4,326,517	06/02/1981 04/27/1982	Romaine	
_		US-			Whitney et al.	
	-	<u> </u>	4,340,048	07/20/1982	Eckenhoff	
	-	US-	4,373,526	02/15/1983	Kling	
	_	US-	4,512,767	04/23/1985	Denance	
-			4,552,561	11/12/1985	Eckenhoff et al.	
		US-	4,734,092	03/29/1988	Millerd	
		US-	4,753,651	06/28/1988	Eckenhoff	
		US-	4,886,499	12/12/1989	Cirelli et al.	
		US-	4,894,054	01/16/1990	Miskinyar	
	<u> </u>	US-	4,955,871	09/11/1990	Thomas	
		US-	4,968,302	11/06/1990	Schluter et al.	<u> </u>
		US-	5,019,047	05/28/1991	Kriesel	
		US-	5,078,680	01/07/1992	Sarnoff	
	-	US-	5,137,516	08/11/1992	Rand et al.	
		US-	5,156,591	10/20/1992	Gross et al.	
			5,167,632	12/01/1992	Eid et al.	
		US-	5,169,389	12/08/1992	Kriesel et al.	
		US-	5,205,820	04/27/1993	Kriesel	
		US-	5,236,419	08/17/1993	Seney	
		US-	5,267,963	12/07/1993	Bachynsky	
	-	US-	5,279,544	01/18/1994	Gross et al.	
		US-	5,279,558	01/18/1994	Kriesel	

Examiner	/Nathan Price/	Date	02/09/2009
Signature		Considered	

				Com	plete if Known
INF	ORMATION	N DIS	CLOSURE	Application Number	10/597,997
	ATEMENT B	. — —-		Filing Date	08/15/2006
SIA) I AI	LICANI	First Named Inventor	Eric James Wall
	(use as many she	ets as neces	sary)	Art Unit	
				Examiner Name	
Sheet	3	of	5	Attorney Docket Number	CHM-022M

Examiner	Cite		Document Number	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where
nitials*	No.1	<u>ļ. </u>	mber - Kind Code² (if known)	MM-DD-YYYY	Applicant of Cited Document	Relevant Passages or Relevant Figures Appear
		US-	5,997,501	12/07/1999	Gross et al.	
		US-	6,042,565	03/28/2000	Hirschman et al.	
		US-	6,048,334	04/11/2000	Hirschman et al.	
		US-	6,077,247	06/20/2000	Marshall et al.	
		US-	6,086,562	07/11/2000	Jacobsen et al.	
		US-	6,132,395	10/17/2000	Landau et al.	
		US-	6,146,361	11/14/2000	DiBiasi et al.	
		US-	6,157,858	12/05/2000	Gross et al.	
		US-	6,186,982B1	02/13/2001	Gross et al.	
		US	6,254,575	07/03/2001	Thorne, Jr. et al.	
		US-	6,264,629 B1	07/24/2001	Landau	
		US-	2001/0012926 A1	08/09/2001	Gross et al.	
		US-	6,312,412	11/06/2001	Saied	
•		US	2001/0039401	11/08/2001	Ferguson et al.	
		US-	6,319,224 B1	11/20/2001	Stout et al.	
		US-	6,364,865 B1	04/02/2002	Lavi et al.	
		US-	2002/0055711 A1	05/09/2002	Lavi et al.	
		US-	2002/0123719 A1	09/05/2002	Lavi et al.	
		US-	6,478,771	11/12/2002	Lavi et al.	
		US-	6,482,176B1	11/19/2002	Wich	
		US-	6,485,461B1	11/26/2002	Mason et al.	
		US-	6,494,865 B1	12/17/2002	Alchas	
•		US-	6,500,150	12/31/2002	Gross et al.	
		US-	2003/0023203 A1	01/30/2003	Lavi et al.	
		US-	6,530,900	03/11/2003	Daily et al.	
		US-	6,530,904B1	03/11/2003	Edwards et al.	
		US-	6,569,123 B2	05/27/2003	Alchas et al.	
		US-	6,569,143 B2	05/27/2003	Alchas et al.	
		US-	2003/0100862A1	05/29/2003	Edwards et al.	
		US-	6,572,740	06/03/2003	Rosenblum et al.	
		US-	2003/0105430 A1	06/05/2003	Lavi et al.	
		US-	2003/0109827 A1	06/12/2003	Lavi et al.	
		US-	6,585,707 B2	07/01/2003	Cabiri et al.	
		US-	6,589,210 B1	07/08/2003	Rolfe	
		US-	6,589,229B1	07/08/2003	Connelly et al.	
		US-	2003/0135159 A1	07/17/2003	Daily et al.	
		US-	6,595,947 Bl	07/22/2003	Mikszta et al.	
		US-	6,595,956B1	07/22/2003	Gross et al.	

Signature Considered 02/09/2009	Signature	/Nathan Price/	Date Considered	02/09/2009
---------------------------------	-----------	----------------	--------------------	------------

				Com	olete if Known
INF	ORMATION	N DIS	CLOSURE	Application Number	10/597,997
	TEMENT B			Filing Date	08/15/2006
SIA) I AI	LICANI	First Named Inventor	Eric James Wall
	(use as many she	ets as neces	sary)	Art Unit	
				Examiner Name	
Sheet	4	of	5	Attorney Docket Number	CHM-022M

U.S. PATENT DOCUMENTS							
Examiner	Cite	Document Number Number - Kind Code ² (if known)		Publication Date MM-DD-YYYY	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	
Initials*	No.1				Applicant of Cited Document		
		US-	6,605,064B2	08/12/2003	Katch		
		US-	2003/0187395A1	10/02/2003	Gabel et al.		
		US-	6,645,180B1	11/11/2003	Hatch		
		US-	6,699,218B2	03/02/2004	Flaherty et al.		
.=-		US-	6,702,779B2	03/09/2004	Connelly et al.		
		US-	6,749,587B2	06/15/2004	Flaherty		

		FOREIG	N PATENT	DOCUMENTS	
Examiner Initials*	Cite No.1	Foreign Patent Document	Publication Date	Name of Patentee or	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	MM-DD-YYYY	Applicant of Cited Document	
		WO 9317754 A1	09/16/1993	Elan Medical Technologies Ltd.	
		WO 9323096 A1	11/25/1993	Gross, Joseph	
WO 9423777 A1 EP 0651667 B1		10/27/1994	Elan Medical Technologies Ltd.		
		05/10/1995	Elan Medical Technologies Ltd.		
		WO 9513838 A1	WO 9513838 A1 05/26/1995 Elan		
		WO 9532013 A1	11/30/1995	Elan Medical Technologies Ltd.	
		WO 9709078 A1	03/13/1997	Elan Medical Technologies Ltd.	
		WO 9710012 A1	03/20/1997	Elan Medical Technologies Ltd.	
		WO 9829662 A1	07/09/1998	Elan Medical Technologies Ltd.	
	WO 9959665 A1		11/25/1999	Elan Corporation, PLC	
		WO 0044437 A1	08/03/2000	Elan Pharma International Ltd.	
		WO 0202165 A2	01/10/2002	Elan Pharma Int'l Ltd.	

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Initials* No 1		nclude name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, nagazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	
		SCARFONE, Richard J., et al., Pain of Local Anesthetics: Rate of Administration and Buffering, Annals of Emergency Medicine, 01/1998, 31.1, 36-40	
		EDLISCH, Richard F., et al., Performance of Disposable Needle Syringe Systems for Local Anesthesia, The Journal of Emergency Medicine, Vol 5 pp. 83-90, 1987	

Examiner	/Nathan Price/	Date	02/09/2009
Signature	//vanian i noo/	Considered	02/09/2009

Receipt date: 03/08/2007 10597997 - GAU: 3763

				Complete if Known		
INF	ORMATION	N DISC	CLOSURE	Application Number	10/597,997	
	TEMENT B			Filing Date	08/15/2006	
) I AI	LICANI	First Named Inventor	Eric James Wall	
	(use as many she	eets as necess	sary)	Art Unit		
				Examiner Name		
Sheet	5	of	5	Attorney Docket Number	CHM-022M	

		OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS	
Examiner Initials*	Cite No.1	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s) volume-issue number(s), publisher, city and/or country where published.	T2
		KRAUSE, Richard S., The Effect of Injection Speed on the Pain of Lidocaine Infiltration, Academic Emergency Medicine, 11/1997, Vol 4/No 11, pgs. 1032-1035	
		MITCHELL, Jane R. et al., The Effect of Injection Speed on the Perception of Intramuscular Injection Pain, AAOHN Journal, 06/01, Vol. 49, NO. 6, pgs. 286-292	
		GRAVEN-NIELSEN, T., et al., In Vivo Model of Muscle Pain: Quantification of Intramuscular Chemical, Electrical, and Pressure Changes Associated with Saline-Induced Muscle Pain in Humans, Pain 69 (1997) pgs. 137-143	
		GRAVEN-NIELSEN, T., et al., Quantification of Local and Referred Muscle Pain in Humans after Sequential i.m. Injections of Hypertonic Saline, Pain 69 (1997) pgs. 111-117	
		CompuDent™, Milestone Scientific, 2002, www.milesci.com/cumpudent/index.php	
		When Patient Care Needs to Be Pain Free, PainFree pump, Sgarlato Labs, www.sgarlatolabs.com/pain_management.shtml, 2 pages; first publication date unknown	
		Uniject TM Injection System Overview, PATH, 8 pages, www.path.org/technos/uniject- overview.htm; first publication date unknown	
		Insulin Pump Technical Specifications, Debiotech S.A., Switzerland, www.debiotech.com/products/msys/ip_page_2.html; March 4, 2002, 1 page	
		MAILLEFER, Didier, et al., A High-Performance Silicon Micropump for Disposable Drug Delivery Systems, 0-7803-5998-4/01 IEEE, pgs. 413-417, 2001	
		The MEDIPAD System Benefits and Applications, Elan Medical Technologies, 990M001, 2002, RevJan2003, 2 pages	
		BD Medical brochure, Franklin Lakes, NJ, www.bd.com, 2003, 1 page	
		National Collegiate Inventors & Innovators Alliance (NCIIA), Advanced E-Team, Grant Profile, Painless Injection Method and Device, publication January 30, 2002, 1 page	
		Beckton, Dickinson and Company brochure, BD™ Disposable Pen, 2000, 2 pages	
		Beckton, Dickinson and Company brochure, BD™ Auto-Injector, 2000, 2 pages	

Examiner Signature	/Nathan Price/	Date Considered	02/09/2009
-----------------------	----------------	--------------------	------------

Receipt date: 03/08/2007

MAR 0 8 2007

COPENDING U.S. PATENT APPLICATIONS						
Examiner Initials*	Applicant(s)	Serial No.	Filing Date	Atty. Docket No.		
	Wall et al.	10/605,187	09/12/2003	CHM-005M		
	Wall et al.	10/597,991	08/15/2006	CHM-021M		

Examiner	/Nathan Price/	Date	02/00/2000
Signature	/Nathan Price/	Considered	02/09/2009